Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRgFUS) for Essential Tremor

Policy Number: PG0440
Last Review: 07/26/2018

GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

SCOPE
X Professional
✓ Facility

DESCRIPTION
Essential tremor (ET) is the most common movement disorder as well as one of the most treated surgically, with an overall prevalence of 0.9%–4.6%. An estimated 25%–55% of ET cases are refractory to medical management. While ET does not shorten life expectancy, the associated disabling symptoms, such as hand tremor, can greatly impact quality of life (functional ADLs, work activities, mood, and socialization). A subset of these patients are candidates for surgical intervention, which includes surgical lesioning and deep brain stimulation (DBS) of the ventral intermediate nucleus of the thalamus. More recently, magnetic resonance-guided focused ultrasound (MRgFUS) thalamotomy has emerged as an alternative therapeutic option for medication-refractory ET.

MRgFUS stereotactic intracranial lesion ablation for movement disorders utilizes multiple elemental arrays of ultrasound transducers to focus thermal ablation to the specific target area as small as millimeters in size. This disturbs the blood-brain barrier, but is noninvasive allowing for an alternative treatment to current open neurologic procedures. Advances in ultrasound transducer design and high-resolution magnetic resonance imaging now allow precise transcranial delivery of high-intensity focused ultrasound. The ultrasound causes a local increase in temperature in the target tissue, resulting in coagulation necrosis while sparing the surrounding normal structures. In addition to providing location guidance, MRI provides real-time clinical monitoring of treatment intensity via thermal imagery.

ExAblate Neuro (InSightec Ltd.) is the only MRgFUS system approved through the Food and Drug Administration (FDA) Premarket Approval (PMA) process for the unilateral thalamotomy treatment of idiopathic essential tremor patients with medication-refractory tremor. MRgFUS is a promising new treatment approach that has attributes, positive and negative, distinct from both traditional thalamotomy and DBS. However, long-term effectiveness and safety remain uncertain and warrant a direct comparison with DBS, the current surgical standard.

POLICY

MRgFUS unilateral thalamotomy (0398T) is non-covered for HMO, PPO, Individual Marketplace, & Advantage.

MRgFUS unilateral thalamotomy (0398T) does not require prior authorization for Elite/ProMedica Medicare Plan.

PG0440 – 12/28/2020
COVERAGE CRITERIA
HMO, PPO, Individual Marketplace, Advantage
Paramount has determined that MRgFUS unilateral thalamotomy is experimental and investigational and therefore non-covered because there is insufficient evidence in the peer-reviewed medical literature of the effectiveness of this procedure.

Elite/ProMedica Medicare Plan
MRgFUS unilateral thalamotomy is considered medically reasonable and necessary in patients with ALL of the following:
1. Medication refractory ET (defined as refractory to at least two trials of medical therapy, including at least one first-line agent)
2. Moderate to severe postural or intention tremor of the dominant hand (defined by a score of ≥2 on the Clinical Rating Scale for Tremor [CRST])
3. Disabling ET (defined by a score of ≥2 on any of the eight items in the disability subsection of the CRST)
4. Not a surgical candidate for DBS (e.g., advanced age, anticoagulant therapy, or surgical comorbidities)

MRgFUS unilateral thalamotomy is considered non-covered for the following:
1. Treatment of head or voice tremor
2. Bilateral thalamotomy
3. Conditions:
   a. A neurodegenerative condition
   b. Unstable cardiac disease
   c. Coagulopathy
   d. Risk factors for deep-vein thrombosis
   e. Severe depression (defined by a score ≥20 on Patient Health Questionnaire 9 (PHQ-9)
   f. Cognitive impairment (defined by a score of <24 on the Mini–Mental State Examination)
   g. Previous brain procedure (transcranial magnetic stimulation, DBS, stereotactic lesioning, or electroconvulsive therapy)
   h. A skull density ratio (the ratio of cortical to cancellous bone) <0.45
   i. MRI contraindicated

CODING/BILLING INFORMATION
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

<table>
<thead>
<tr>
<th>CPT CODE</th>
<th>Description</th>
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<tbody>
<tr>
<td>0398T</td>
<td>Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed</td>
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<table>
<thead>
<tr>
<th>ICD-10-CM CODE</th>
<th>Description</th>
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<tr>
<td>G25.0</td>
<td>Essential tremor</td>
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REVISION HISTORY EXPLANATION
ORIGINAL EFFECTIVE DATE: 07/26/2018
07/26/18: MRgFUS unilateral thalamotomy (0398T) is covered without prior authorization for Elite per CMS guidelines and non-covered for HMO, PPO, Individual Marketplace, & Advantage. Policy created to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).
12/28/2020: Medical policy placed on the new Paramount Medical policy format
REFERENCES/RESOURCES
Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid
Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets
Industry Standard Review
Hayes, Inc.